

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Comparison of the effect of two methods of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students with premenstrual syndrome.

#### Protocol summary

##### Study aim

1-comparison of depression score before and after intervention in cognitive-behavioral group therapy in female students with premenstrual syndrome 2- comparison of depression scores before and after cognitive hypnosis intervention in female students with premenstrual syndrome 3- comparison of depression score in two cognitive-behavioral therapy groups and cognitive hypnosis in female students with premenstrual syndrome

##### Design

community-based and pragmatic control group, with parallel groups, blinded and randomized.

##### Settings and conduct

The aim of this study was to compare the effects of two methods of cognitive-behavioral group therapy and group cognitive hypnosis on depression in female students in 2018 in Islamic Azad University. The type of research is experimental . The study groups consisted of two experimental groups and one control group, who were not aware of the inclusion of one-way blind in intervention groups and only participated in a study to study the premenstrual syndrome.

##### Participants/Inclusion and exclusion criteria

Entering the study include being a student in one of the psychology courses, ages 18 to 50, the absence of mental disorders, including depression and PMS in the family, and the lack of drug use, and the exit criterion is the existence of a negative Spigel test for hypnosis.

##### Intervention groups

The first test group (cognitive-behavioral group therapy)  
The second test group ( group of cognitive hypnosis treatment) The control group(non intervention)

##### Main outcome variables

Comparison of the Effect of Two Psychological Therapies on depression; The Effect of Two Psychological Therapies on depression in Students

#### General information

##### Reason for update

##### Acronym

PMS

##### IRCT registration information

IRCT registration number: **IRCT2016090228931N1**

Registration date: **2016-09-02, 1395/06/12**

Registration timing: **prospective**

Last update: **2018-04-29, 1397/02/09**

Update count: **1**

##### Registration date

2016-09-02, 1395/06/12

##### Registrant information

##### Name

Leila Moghtader

##### Name of organization / entity

Azad University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 13 3350 1139

##### Email address

moghtaderleila@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Rasht Azad University of Medical Sciences

##### Expected recruitment start date

2018-05-21, 1397/02/31

##### Expected recruitment end date

2018-06-21, 1397/03/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of two methods of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students with premenstrual syndrome.

**Public title**

Comparison of group cognitive- behavioral therapy and group cognitive hypnotism on Degree of depression in girl students.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being a student in one of the psychology courses aged 18 to 50 years lack of medication

**Exclusion criteria:**

negative spiegel test for hypnosis

**Age**

From **18 years** old to **50 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this research, simple randomization method will be used. In this way, people in the test and control groups or lottery will be selected and will be replaced by lottery in these groups. Accident Unit: Individual Randomization Tool: Draw a random numbered table Participants will not be aware of the status of the target group until the completion of the study.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants will not be aware of the status of the target group until the completion of the study.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

After sampling, two experimental groups and one control group will be separat by lottery

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Rasht University of Medical Sciences

**Street address**

Rasht, Pole Taleshan, Azad University

**City**

Rasht

**Province**

Guilan

**Postal code**

4154974416

**Approval date**

2016-08-10, 1395/05/20

**Ethics committee reference number**

IR.GUMS.REC.1396.534

**Health conditions studied****1****Description of health condition studied**

Premenstrual Syndrome

**ICD-10 code**

F99

**ICD-10 code description**

Mental disorder, not otherwise specified

**Primary outcomes****1****Description**

Depression

**Timepoint**

Before and after the intervention

**Method of measurement**

Beck Depression Inventory

**Secondary outcomes**

empty

**Intervention groups****1****Description**

The first experimental group: eight 2-hour sessions of cognitive behavior therapy

**Category**

Behavior

**2****Description**

The first experimental group: eight 2-hour sessions of Cognitive Hypnotherapy

**Category**  
Behavior

**3**

**Description**  
No action

**Category**  
N/A

## Recruitment centers

**1**

### Recruitment center

**Name of recruitment center**  
Holistic Nursing Research Center

**Full name of responsible person**  
Sedigheh Pakseresht

**Street address**  
Rasht, belt martyr Beheshti, Faculty of Nursing and Midwifery

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moghtaderleila@yahoo.com

## Sponsors / Funding sources

**1**

### Sponsor

**Name of organization / entity**  
Vice Chancellor for research of Gilan University of Medical Sciences

**Full name of responsible person**  
Sedigheh Pakseresht

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**Grant name**  
Guilan University of Medical Science

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**  
Yes

**Title of funding source**  
Vice Chancellor for research of Gilan University of Medical Sciences

**Proportion provided by this source**  
100

**Public or private sector**  
Public

**Domestic or foreign origin**  
Domestic

**Category of foreign source of funding**  
*empty*

**Country of origin**

**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Azad University

**Full name of responsible person**  
Leila Moghtader

**Position**  
Assistant Professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Psychology

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## Person responsible for scientific inquiries

### Contact

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ph.D psychology

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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**Postal code**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available